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10/531,546	10/21/2005	William R. Freeman	1034123-000153	3894

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
05/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,546	FREEMAN, WILLIAM R.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37 and 40-42* is/are pending in the application.

4a) Of the above claim(s) *19-23,25-37 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 24, 41-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed 2/12/2008 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 1, 15, and 24 have been amended.

   b. Claims 38-39 have been cancelled.

   c. Claims 41-42 has been added.

2. Claims 1-37 and 40-42 are pending in the case.

3. Claims 1-18, 24, and 41-42 and are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

6. Applicant's arguments with respect to claims 1-18 and 24 have been considered but are moot in view of the new grounds of rejection.

7. Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to the dose of the

photoactivating light wherein the dose is 50 j/cm^{2,} 100 j/cm^{2,} 125 j/cm^{2,} or 150 j/cm^{2}. It is unclear what is the dosage/fluence claimed. It does not allow one of skill in the art to ascertain the metes and bounds of the invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-8, 10-12, 14, 16-17, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin).

Levy et al. teaches a method of photodynamic therapy for unwanted neovasculature in the eye specifically in Age-related macular degeneration. Fundus photography, histological examination, and fluorescein angiography were used to observe and identify the choroidal revascularization. A green porphyrin, BPD-MA (verteporfin), was combined with lipoproteins, and injected intravenously in a leg vein. The eyes were then irradiated with a laser at 692 nm to treat the areas of choroidal neovascularization. The fluence for the treatment sites in the examples were 50, 75, 100 or 150 joules/cm^{2}. Subsequent angiography was used to show the closure of the vasculature (Abstract, Col.1, lines 18-48, 55-63, Col. 2, lines 13-32, 39-52, Col. 3, lines

32-40, 45-68, Col. 4, lines 1-64, Col. 6, lines 1-36, Col. 8, lines 26-45, Examples 1-2, Col. 9-10, Example 3 and 4, Col. 11 Table 5).

Levy et al. does not expressly teach the method for treating an aberrant choridal neovasculature in an extrafoveal area of the eye.

Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) teaches that photodynamic therapy (PDT) with verteporfin is well-known for treating patient with subfoveal choroidal neovascularization (CNV) and should be considered for the therapy of CNV that is not subfoveal in certain situation such as juxtafoveal and extrafoveal CNV. Jampol teaches that there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result. Jampol teaches that the combination of therapies could be more beneficial than either alone. Additionally, it may be possible to treat a juxtafoveal or extrafoveal membrane with PCT first and see the results. If the lesion continues to grow, then thermal lasers could be considered as a next step if needed. The reverse is also contemplated, whereby treatment with the laser is not successful, PDT with verteporfin would be considered. Jampol also addressed that the PDT outcome for extrafoveal CNV lesions would be better than with subfoveal, and juxtafoveal area would be with an intermediate result (Pages 99-101).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize photodynamic therapy for CNV in the extrafoveal area of the eye, as suggested by Jampol et al., and produce the instant invention. It would have been obvious to utilize the PDT in the extrafoveal region as CNV lesions in the eye would be expected to have better favorable outcomes even compared to the classic subfoveal and could allow the survival of the retina over the CNV.

One of ordinary skill in the art would have been motivated to do this because as taught by Jampol, there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal lasers produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result, such as extrafoveal and juxtafoveal CNV.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 1-8, 10-12, 14, 16-17, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of

Photodynamic Therapy With Verteporfin) and further in view of Miller et al. (U.S. Pat. No. 5707986).

Sullivan teaches the method of treating choroidal neovascularization caused by age-related macular degeneration. The method utilized fluorescein angiograms to determine the presence, location, and extent of the choroidal neovascularization by injection of a dye into a vein and multiple photographs of the retina. Treatment followed with the use of photodynamic therapy utilizing verteporfin coupled with low-density lipoprotein and injected intravenously. A non-thermal laser light was then used to activate the verteporfin at the area of neovascularization. The wavelength used was 689 nm, corresponding to the absorption peak of the verteporfin dye. The result was thrombosis and occlusion of the abnormal vessel (Pages 396-398).

Sullivan et al. does not expressly teach the method for treating an aberrant choridal neovasculature in an extrafoveal area of the eye or the fluence of the photoactivating light.

Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) teaches that photodynamic therapy (PDT) with verteporfin is well-known for treating patient with subfoveal choroidal neovascularization (CNV) and should be considered for the therapy of CNV that is not subfoveal in certain situation such as juxtafoveal and extrafoveal CNV. Jampol teaches that there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal laser produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over

the CNV, and that successful PDT with verteporfin could allow for a better result. Jampol teaches that the combination of therapies could be more beneficial than either alone. Additionally, it may be possible to treat a juxtafoveal or extrafoveal membrane with PCT first and see the results. If the lesion continues to grow, then thermal lasers could be considered as a next step if needed. The reverse is also contemplated, whereby treatment with the laser is not successful, then PDT with verteporfin would be considered. Jampol also addressed that the PDT outcome for extrafoveal CNV lesions would be better than with subfoveal, and juxtafoveal area would be with an intermediate result (Pages 99-101).

Miller et al. teaches the use of a green porphyrin, BPD-MA (verteporfin) for treating the choroidal neovasularization and other conditions. The BPD-MA was combined with lipoproteins, and injected intravenously in a leg vein. The eyes were then irradiated with a laser at 692 nm to treat the areas of choroidal neovascularization. Miller teaches that the porphyrin is used within the range of about 0.1 to about 20mg/kg, preferably from about 0.15-2.0mg/kg. Specifically, when the green porphyrin dose is reduced from about 2 to about 1mg/kg, there is a corresponding increase in the fluence required to close the choroidal neovascular tissue, such as from about 50 J/cm^2 to about 100J/cm^2. The green porphyrin has a maximum absorbance of about 550 to 695nm which is the wavelength used to radiate the porphyrin. The fluence for treatment can vary depending the tissue, depth, and amount of fluid/blood, but preferably varies from about 50-200 J/cm^2. The examples utilized for the treatment sites, verteporfin irradiated with a wavelength of 692, and fluences of 50, 100, and 150 $joules/cm^2$ were

utilized to effectively close the choroidal neovascularization. Subsequent angiography was used to show the closure of the vasculature (Abstract, Col.3, lines 1-68, Col. 4, lines 1-33, Col. 5, lines 29-55, Col. 7, lines 17-65, Col. 8, lines 55-68, Col.10-12, Example 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize photodynamic therapy for CNV in the extrafoveal area of the eye, as suggested by Jampol et al., with the fluence levels as suggested by Miller, and produce the instant invention. It would have been obvious to utilize the PDT in the extrafoveal region as CNV lesions in the eye would be expected to have better favorable outcomes even compared to the classic subfoveal and could allow the survival of the retina over the CNV. It would have been obvious to use the effective fluence amounts of photoactive light for irradiation of verteporfin to close the choroidal neovascularization. It is obvious to use the amounts and ranges taught by Miller for the fluence as the dye (verteporfin) utilized is the same, with photoactive light in the same wavelength ranges taught, and for the same purpose for the same conditions to yield the same result, the closure of the abnormal vasculature.

One of ordinary skill in the art would have been motivated to do this because as taught by Jampol, there are some situations where the use of PDT with verteporfin would be particularly desirable as thermal laser produce an absolute scotoma verses PDT with verteporfin which could allow the survival of the retina over the CNV, and that successful PDT with verteporfin could allow for a better result, such as extrafoveal and juxtafoveal CNV. One would also be motivated to use known amounts and technique for

the same treatment with the taught amounts and ranges to be effective for closure of the choroidal neovascularization.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) as applied to claims 1-8, 10-12, 14, 16-17, 24, 41-42 above, and in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Levy et al. in view of Jampol et al. are discussed above.

Levy et al. in view of Jampol et al. does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143), which is fully incorporated by reference in Levy et al. (U.S. Pat. No. 5798349), teaches that the photosensitizing compounds can be administered for systemic or topical use in formulations well know in the art (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and produce the instant invention. It would have obvious to try topical administration as it would be another method of administration if adequate intravenous lines would not be available such as collapsed veins.

One of ordinary skill in the art would have been motivated to do this because topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) and in view of Miller et al. (U.S. Pat. No. 5707986) as applied to claims 1-8, 10-12, 14, 16-17, 24, 41-42 above, and further in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Sullivan, Jampol et al., and Miller et al. are discussed above.

Sullivan, in view of Jampol et al., in view of Miller et al. does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143 teaches that the photosensitizing compounds can be administered in formulations well known in the art for systemic or topical use (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and produce the instant invention. It would have obvious to try topical administration as it would be another method of administration if adequate intravenous lines would not be available such as collapsed veins.

One of ordinary skill in the art would have been motivated to do this because topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) as applied to claims 1-8, 10-12, 14, 16-17, 24, 41-42 above, and in view of Roach (EyeNet Magazine March 2001).

The teachings of Levy et al. (U.S. Pat. No. 5798349) and Jampol et al. are discussed above. Levy also teaches that laser photocoagulation treatment is also available for the condition due to the side effects, scarring, and level of prognosis, strategies such as photodynamic therapy are desirable since there is greater selective closure of the blood vessels.

Levy in view of Jampol et al. does not expressly teach the use of high speed scanning laser ophthalmoscope or the use of indocyanine green.

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you cannot. Roach teaches that real-time digital imaging systems for high-speed indocyanine green angiography (HSICG) coupled with a scanning laser ophthalmoscope can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize high-speed indocyanine green angiography, as suggested by Roach, and produce the instant invention. While described for laser

photocoagulation treatment, it would have obvious to one of skill in the art that the imaging technique would also be invaluable in photodynamic therapy to improve the accuracy and images available to the practitioner to diagnosis and perform the therapy effectively.

One of ordinary skill in the art would have been motivated to do this because Roach teaches that because the system operates in real time, it is possible to immediately treat an area as it is identified. The system also allows the practitioner to increase number of vessels to be treated since it increases the number of vessel you can see.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) and in view of Miller et al. (U.S. Pat. No. 5707986) as applied to claims 1-8,

10-12, 14, 16-17, 24, 41-42 above, and further in view of Roach (EyeNet Magazine March 2001).

The teachings of Sullivan, Jampol et al., and Miller et al. are discussed above. Sullivan also teaches that laser photocoagulation treatment is also available for the condition but less than 20% of patients meet the eligibility criteria.

Sullivan, in view of Jampol et al., and further in view of Miller et al. does not expressly teach the use of high speed scanning laser ophthalmoscope or the use of indocyanine green.

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you can't.

Roach teaches that real-time digital imaging systems for high-speed indocyanine green angiography (HSICG) coupled with a scanning laser ophthalmoscope can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize high-speed indocyanine green angiography, as suggested by Roach, and produce the instant invention. While described for laser photocoagulation treatment, it would have obvious to one of skill in the art that the imaging technique would also be invaluable in photodynamic therapy to improve the

accuracy and images available to the practitioner to diagnosis and perform the therapy effectively.

One of ordinary skill in the art would have been motivated to do this because Roach teaches that because the system operates in real time, it is possible to immediately treat an area as it is identified. The system allows the practitioner to increase number of vessels to be treated since it increases the number of vessel you can see.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) as applied to claims 1-8, 10-12, 14, 16-17, 24, 41-42 above, and in view of LumaCare (Press release - http://lumacare.com/EMEA/pr3.html).

The teachings of Levy et al. in view of Jampol et al. are discussed above. Levy also teaches the use of coherent light (lasers) in photodynamic therapy.

Levy et al. in view of Jampol et al. does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective.

One of ordinary skill in the art would have been motivated to do this because not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases efficiency, and increases productivity of the practitioner thereby providing more income, a very strong motivation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the

teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

18. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) and further in view of Miller et al. (U.S. Pat. No. 5707986) as applied to claims 1-8, 10-12, 14, 16-17, 24, 41-42 above, and in view of LumaCare (http://lumacare.com/EMEA/pr3.html).

The teachings of Sullivan, Jampol et al., and Miller et al. are discussed above. Sullivan, Jampol et al., and Miller et al. teach the use of coherent light (lasers) in photodynamic therapy.

Sullivan, in view of Jampol et al., and further in view of Miller et al. does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective.

One of ordinary skill in the art would have been motivated to do this because not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases efficiency, and increases productivity of the practitioner thereby providing more income, a very strong motivation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

19. Claims 1-18, 24, and 41-42 are rejected.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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